UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,256	05/05/2006	Maria T. Abreu	025663-001310US	7450

20350 7590 08/25/2009

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
GOLDBERG, JEANINE ANNE	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
08/25/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,256	ABREU ET AL.	
	Examiner	Art Unit	
	JEANINE A. GOLDBERG	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/29/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,16-18,20-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-26 and 28-30* is/are allowed.

6)☒ Claim(s) *1,4,16-18, 20-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the papers filed May 29, 2009.

2. Currently, claims 1, 4, 16-18, 20-26, 28-30 are pending.

3. In view of the papers filed October 9, 2008, the inventorship in this nonprovisional application has been changed by the deletion of Kazuhito Sugimura.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected

4. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.

5. Any objections and rejections not reiterated below are hereby withdrawn.

a. The 102(a) rejection over Abreu has been withdrawn in view of the declaration filed on October 9, 2008 by Dr. Kent Taylor and in view of the statement under Rule 1.48(b) removing Sugimura from the inventive entity. Therefore, the declarations under 37 CFR 1.132 filed executed on September 20, 2007 is sufficient to overcome the rejections. The declaration executed September 20, 2007 clearly states that Dr. Lin, Hang, Gaiennie, Vasiliauskas, Kam, Rojany, Papadakis are not co-inventors which clearly removes these co-authors.

Priority

6. This application is a 371 of PCT/US03/23926, filed July 30, 2003 and claims priority to 10/356736, filed January 30, 2003 and provisional application 60/407,391, filed August 30, 2002.

Drawings

7. The drawings are acceptable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 1, 4, 16-18, 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Ahmad et al. (Gastroenterology, Vol. 122, pages 854-866, April 2002).

The claims appear to have been amended to require an association of Crohn's disease characterized by fibrostenosing disease independent of small bowel involvement. It is not clear how this changes the scope of the instant claims, as this appears to be consistent with fibrostenosing disease. This does not appear to add any particular limitation of obtaining a patient without small bowel disease, it merely requires that the association is independent of small bowel disease.

Ahmad et al. teaches the molecular classification of the clinical manifestations of Crohn's disease. Ahmad teaches genotyping using PCR primers (limitations of Claim 19). Table 9 illustrate surgical stenotic disease and analyzes 1007fsincC; 908Arg and

702Trp. 1007fsincC appears to have a statistically significant association of $p<0.0001$. 908Arg appears to have a statistical significant association with $p<0.001$. Ahmad teaches stenotic disease was positively associated with the presence of a NOD2/CARD15 mutation, but this was not independent of the link with ileal disease. No other independent associations were found with disease behavior phenotypes (page 864, col. 1).

Response to Arguments

The response traverses the rejection. The response asserts that the Abreu reference was received on February 8, 2002 and paragraph 12 of Dr. Taylors 1.132 Declaration of record is sufficient to overcome the 102(a) rejections. This argument has been considered but is not convincing because the MPEP clearly provides that to antedate a reference a 1.131 Declaration is required. It is also noted that 1.131 declarations must be signed by all the inventors and must be established in the US, a NAFTAS country or a WTO member county. See 37 C.F.R. 1.131 and MPEP 715. Here, the declaration by Dr. Taylor alone does not provide where the prior invention was established. 37 C.F.R. 131 declarations should be made by all the inventors unless less than all named inventors of an application invented the subject matter of the claim or claims under rejection. Here, there is no showing that less than all the inventors invented the subject matter. Thus, the declaration should be signed by all the inventors. See MPEP 715.04. Moreover, it is noted that under 1.131, "the showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference… Original exhibits of drawing or records, or photocopies

thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained."

As provided in 715.09, "Affidavits or declarations under 37 CFR 1.131 must be timely presented in order to be admitted. Affidavits and declarations submitted under 37 CFR 1.131 and other evidence traversing rejections are considered timely if submitted:

(A) prior to a final rejection;

(B) before appeal in an application not having a final rejection; *

(C) after final rejection **>, but before or on the same date of filing an appeal, upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented in compliance with 37 CFR 1.116(e); or

(D) after the prosecution is closed (e.g., after a final rejection, after appeal, or after allowance) if applicant files the affidavit or other evidence with a request for continued examination (RCE) under 37 CFR 1.114 in a utility or plant application filed on or after June 8, 1995; or a continued prosecution application (CPA) under 37 CFR 1.53(d) in a design application.

Thus for the reasons above and those already of record, the rejection is maintained.

9. Claims 1, 4, 16-18, 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Radlmayr et al. (Gastroenterology, Vol. 122, No. 7, pages 2091-2095, June 2002).

The claims appear to have been amended to require an association of Crohn's disease characterized by fibrostenosing disease independent of small bowel involvement. It is not clear how this changes the scope of the instant claims, as this

appears to be consistent with fibrostenosing disease. This does not appear to add any particular limitation of obtaining a patient without small bowel disease, it merely requires that the association is independent of small bowel disease.

Radlmayr et al. teaches the c-insertion mutation of the NOD2 gene is associated with fistulizing and fibrostenotic phenotypes in Crohn's disease. Radlmayr teaches patients with Crohn's disease were subdivided according to their respective phenotypes, e.g., fistulizing, fibrostenotic, or inflammatory by conventional clinical, endoscopic, radiologic, and histological criteria. When patients with Crohn's disease were stratified according to the respective disease phenotype, the c-insertion mutation was associated with the fibrostenotic phenotype (p=0.023)(page 2091, col. 2). As seen in Table 1, the number of patients with or without the c-insertion allele according to the diseases were compared (page 2092, col. 1).

Response to Arguments

The response traverses the rejection. The response asserts that the Abreu reference was received on February 8, 2002 and paragraph 12 of Dr. Taylors 1.132 Declaration of record is sufficient to overcome the 102(a) rejections. This argument has been considered but is not convincing because the MPEP clearly provides that to antedate a reference a 1.131 Declaration is required. It is also noted that 1.131 declarations must be signed by all the inventors and must be established in the US, a NAFTAS country or a WTO member county. See 37 C.F.R. 1.131 and MPEP 715. Here, the declaration by Dr. Taylor alone does not provide where the prior invention was established. 37 C.F.R. 131 declarations should be made by all the inventors unless

less than all named inventors of an application invented the subject matter of the claim or claims under rejection. Here, there is no showing that less than all the inventors invented the subject matter. Thus, the declaration should be signed by all the inventors. See MPEP 715.04. Moreover, it is noted that under 1.131, "the showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference… Original exhibits of drawing or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence must be satisfactorily explained."

As provided in 715.09, "Affidavits or declarations under 37 CFR 1.131 must be timely presented in order to be admitted. Affidavits and declarations submitted under 37 CFR 1.131 and other evidence traversing rejections are considered timely if submitted:

(A) prior to a final rejection;

(B) before appeal in an application not having a final rejection; *

(C) after final rejection **>, but before or on the same date of filing an appeal, upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented in compliance with 37 CFR 1.116(e); or

(D) after the prosecution is closed (e.g., after a final rejection, after appeal, or after allowance) if applicant files the affidavit or other evidence with a request for continued examination (RCE) under 37 CFR 1.114 in a utility or plant application filed on or after June 8, 1995; or a continued prosecution application (CPA) under 37 CFR 1.53(d) in a design application.

Thus for the reasons above and those already of record, the rejection is maintained.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Doug Schultz, can be reached on (571)272-0763.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

/Jeanine Goldberg/
Primary Examiner
August 24, 2009